Publications on proficiency testing

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Agenda

- ISO Standards
- ILAC guidance documents
- EA guidance documents
- Eurachem guidance documents

ISO Standards

INTERNATIONAL STANDARD

ISO/IEC 17043

First edition
2010-02-01

Conformity assessment — General requirements for proficiency testing

Évaluation de la conformité — Exigences générales concernant les essais d'aptitude

Reference number
ISO/IEC 17043:2010(E)

BS ISO 13528:2015

INTERNATIONAL STANDARD

ISO 13528

Second edition
2015-08-01

Statistical methods for use in proficiency testing by interlaboratory comparison

Méthodes statistiques utilisées dans les essais d'aptitude par comparaison interlaboratoires

Reference number
ISO 13528:2015(E)

ISO/IEC 17043 – the requirements

- **Technical Requirements**
  - Personnel
  - Equipment, accommodation & environment
  - Design of PT schemes
  - Choice of method or procedure
  - Operation of PT schemes
  - Data analysis and evaluation of PT scheme results
  - Reports
  - Communication with participants
  - Confidentiality

Revision likely to start in 2020

- **Management Requirements**
  - Organization
  - Management system
  - Document control
  - Review of requests, tenders & contracts
  - Subcontracting services
  - Purchasing services and supplies
  - Service to the customer
  - Complaints and appeals
  - Control of nonconforming work
  - Improvement
  - Corrective actions
  - Preventive actions
  - Control of records
  - Internal audits
  - Management reviews

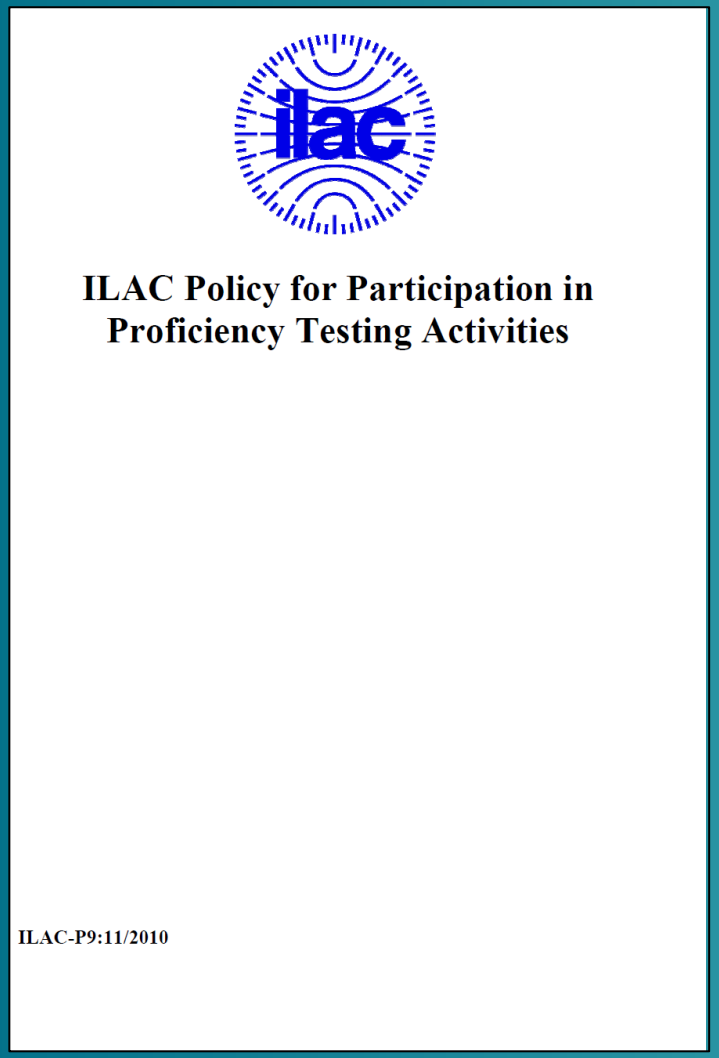
ISO/IEC 13528 – the requirements

- **Split into a number of sections**
  - General principles
  - Guidelines for the statistical design of proficiency testing schemes
  - Guidelines for the initial review of proficiency testing items and results
  - Determination of the assigned value and its standard uncertainty
  - Determination of criteria for the evaluation of performance
  - Calculation of performance statistics
  - Graphical methods for describing performance scores
  - Design and analysis of qualitative proficiency testing schemes

- **Annexes**
  - Symbols
  - Homogeneity and stability of proficiency test items
  - Robust analysis
  - Additional guidance on statistical procedures
  - Illustrative examples

Revision to start in 2019

ILAC guidance documents

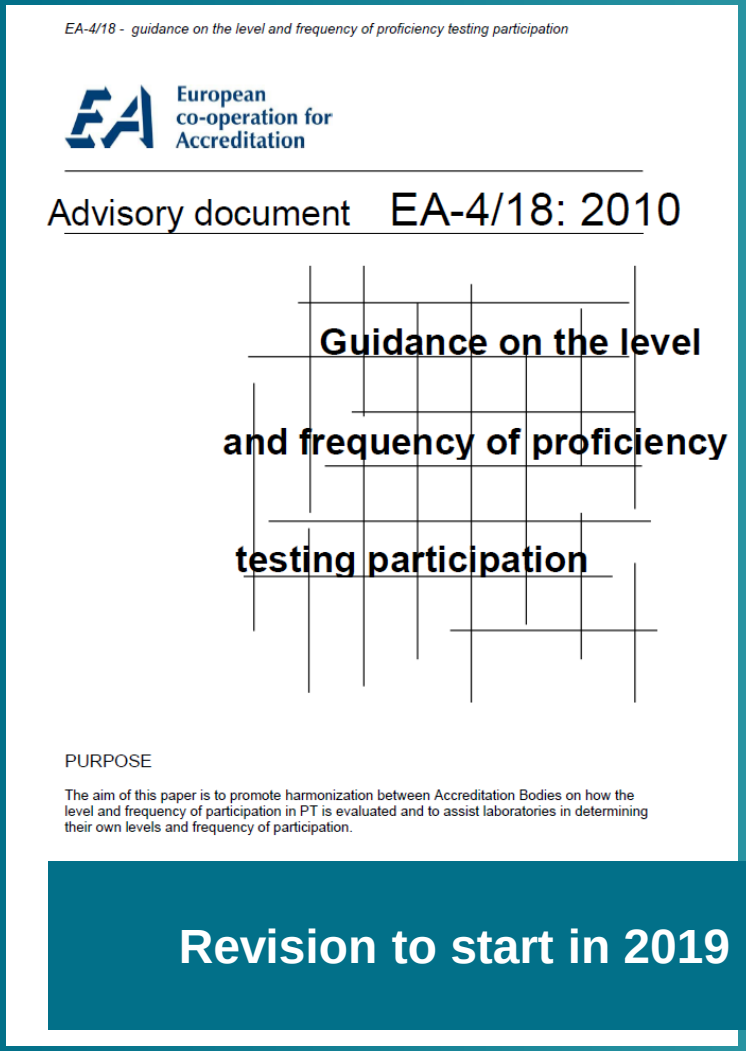


- Sets out the requirements for, and gives guidance to accreditation bodies, on the use of proficiency testing activities in the accreditation process of laboratories.

- It also aims to assist accreditation bodies to consistently apply define and apply relevant PT policies

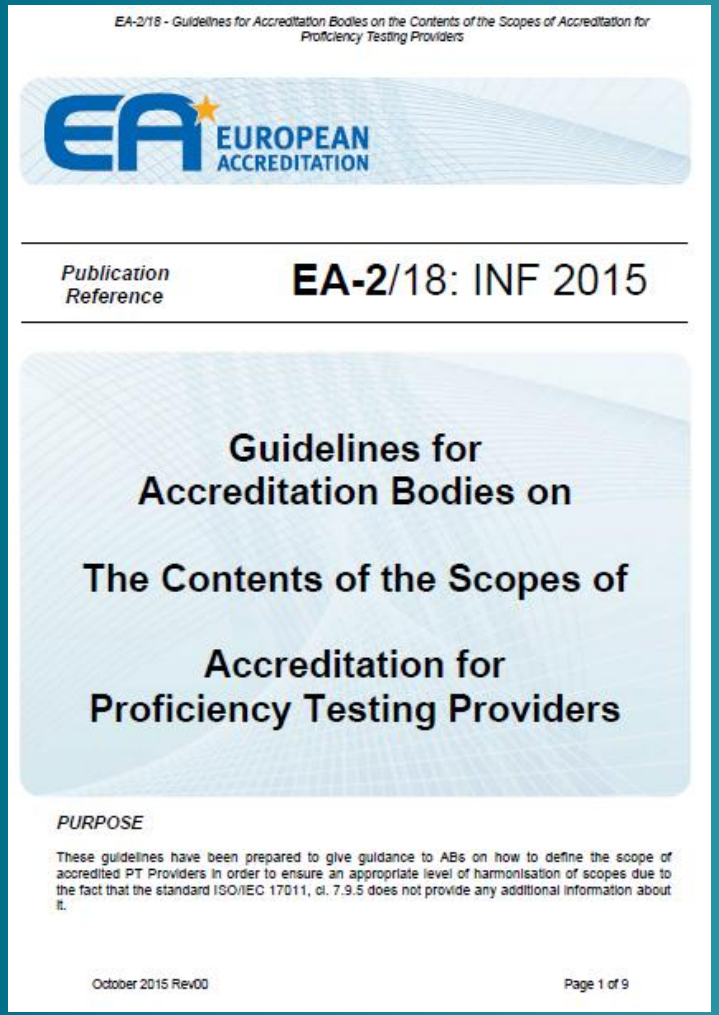
Revision to start in 2019

EA guidance documents



Revision to start in 2019

- Uses a risk based approach to deciding the laboratory participation strategy
- A laboratory should decide on an appropriate level and frequency of participation:
  - **Level:** number of specific proficiency tests in which to participate
  - **Frequency:** How often the laboratory will participate in each of the specific test identified



EA-2/18 - Guidelines for Accreditation Bodies on the Contents of the Scopes of Accreditation for Proficiency Testing Providers

EUROPEAN ACCREDITATION

Publication Reference **EA-2/18: INF 2015**

Guidelines for Accreditation Bodies on The Contents of the Scopes of Accreditation for Proficiency Testing Providers

PURPOSE

These guidelines have been prepared to give guidance to ABs on how to define the scope of accredited PT Providers in order to ensure an appropriate level of harmonisation of scopes due to the fact that the standard ISO/IEC 17011, cl. 7.9.5 does not provide any additional information about it.

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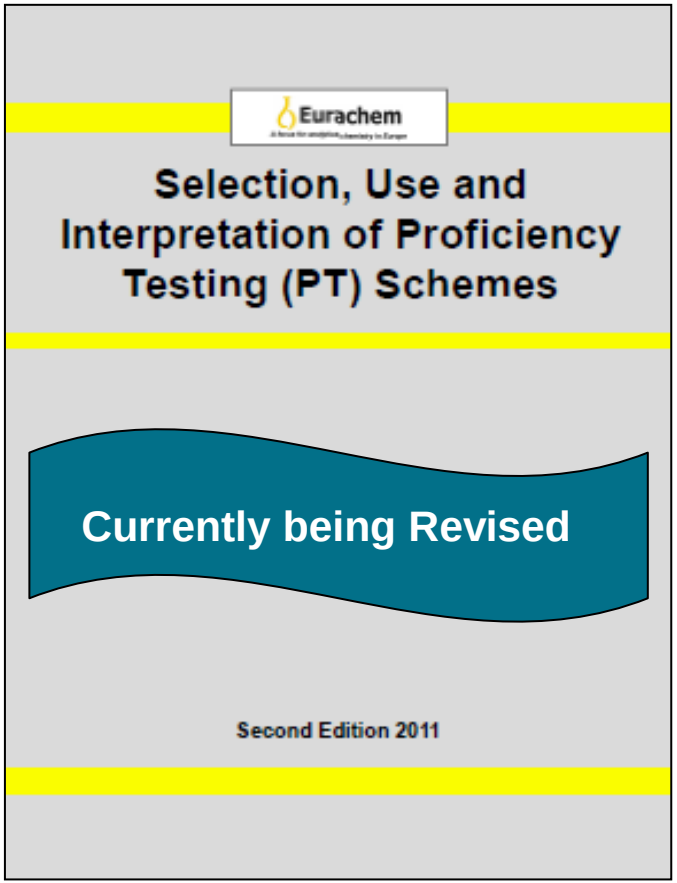
- Provides guidance on the contents of the scopes of accreditation for PT providers
- Encourages accreditation bodies to grant an appropriate level of flexibility to aid development of the PT schemes
- The following information should be available:
  - Accreditation Number
  - Accreditation Standard
  - Name & address of PT provider
  - Date(s)
  - PT scheme identification
  - Technical field
  - Test item
  - Property/Quantity
  - Contact details

Eurachem guidance documents

PT Guide



- **Main sections**
  - Introduction to proficiency testing
  - Selection of PT schemes
  - Use of PT by laboratories
  - How a PT provider evaluates the laboratory's performance
  - Laboratory interpretation of PT results

- **Appendices**
  - Selection form for a relevant PT scheme
  - Form for documenting PT investigations
  - Interpretation of PT data by end-users
  - Statistical aspects of PT
  - Performance evaluation of PT
  - Examples of different evaluation approaches
  - Examples of long-term performance evaluation
  - Example of the use of measurement uncertainty

PT Leaflets

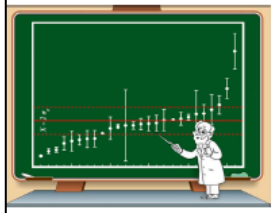
How can proficiency … help my laborato…

Introduction

Proficiency testing (PT) is applicable to quantitative, qualitative and interp… this leaflet will concentrate on PTs for quantitative tests. Participation in PT … quality assurance in analytical laboratories and provides them with many b… evaluates the participants performance against pre-established criteria de… PT scheme.

Performance evaluation

The majority of PT schemes involve some form of performance score, such … and corresponding assessment criteria. An assigned value X and a standar… assessment are determined and used for calculating the performance score … e.g. the z-score with $z = (x - X) / \sigma_p$



Assessment of z-s… following criteria:

- $|z\text{-score}| \leq 2.0$ is …
- $2.0 < |z\text{-score}| <$ … questionable ('wa…
- $|z\text{-score}| \geq 3.0$ is … unsatisfactory ('ac…

This is based on t… distributed analytica… standard deviations … %, and within three… a probability of 99.7…

PT providers have several options to determine σ_p such as prescribed/per… performance or the observed distribution of data. The σ_p used by the … appropriate for all laboratories. If justified, the participants may then ca… using an alternative σ_p-value which is fit for their purpose.

Corrective actions

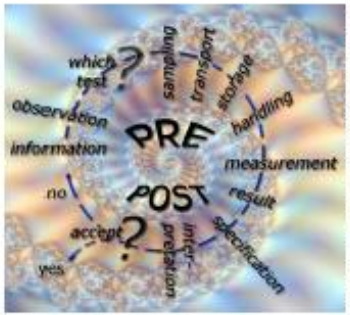
Unsatisfactory performance scores ('action signal') indicate possible p… the analysis undertaken. The laboratory must investigate this (e.g. by c… transcription/calculation errors, trueness and precision) and, if necessary, a… problems through appropriate corrective actions. Participation in the PT pr… limited benefits to the laboratory, if unsatisfactory performance scores are … upon.

[1] For other scores refer to ISO 13528

Pre- and post-anal… proficiency test…

Introduction

Routine chemical analysis typically involves several steps, e.g. selecti… sample preparation, measurement, result calculation, uncertainty est… tomer. Based on the result, important decisions and actions are taken … the measurement are often referred to as "pre- and post-analytical". … uncertainty associated with this work, some of which can actually lim…



The examples in this leaflet illustrates their potential and importance … PT/EQA. They are intended as an inspiration for the providers to furth… quality control activities.

Pre- and post-analytical PT/EQA – a means for h…

By illustrating, e.g. lack of adherence to guidelines, or variation in sa… preparation, or inconsistency in interpretation, pre- and post-analytica… schemes pinpoint problems not apparent in other schemes. This may … improved harmonisation and changes to guidelines and standards.

Selecting the right proficien… testing scheme for my labora…

Introduction

Participation in Proficiency Testing (PT) is an important part of assuring the quality of test results in a laboratory. The time and effort required can be costly, especially for laboratories performing many different tests, so selecting the most appropriate PT scheme is very important. Several PT schemes are often available for the same area of testing, so this leaflet focuses on key questions that can help laboratories choose those PT schemes that are best suited for their needs.

Parameters included in the PT

Are the matrices, analytes, and/or concentration levels of the test items offered … similar to those of samples encountered in the everyday practice of the laboratory? …

Example 1: *The levels of contaminants in a PT scheme for drinking water will be quite different from those expected in industrial wastes.*

A laboratory testing industrial wastes could:
- Participate, taking into account the limitations
- Not participate at all

Example 2: *PT schemes for DNA may offer either tissue … extracts.*

Depending on its choice, t… competence will be assess…
- The whole test
- The sequencing step on…

Strategies for data collection and analysis

Are the strategies applied by the PT provider suitable for the needs of the laboratory … Factors to be considered include:

- Description of the statistical design applied
- Number of test items to be analysed and/or number of replicates requested
- Procedures for data collection from participants (e.g. submission by fax, e-mails …
- Procedures for comparison of results obtained by different methods/techniques
- Number and origin of participants
- Number of participants using the same method/technique as the laboratory
- Methods and criteria used for performance assessment

The laboratory should also consider whether its customers, accreditation bodies and/or regulatory bodies have any specific requirements on statistical design.

Example 3: *A laboratory determines the fat content in milk powder, cereals and feed using three operationally defined methods, Röse Gottlieb, direct fat extraction and fat determination by hydrolysis. Each method could give different results for each matrix. It is important for the laboratory to check whether the different testing methods are taken into consideration for each matrix in the PT scheme.*

Proficiency testing – How much and how often?

Introduction

An accredited laboratory needs to define in which PT schemes it should enrol (**level**) and how often (**frequency**). This is addressed in the advisory document EA-4/18 from the European Co-operation for Accreditation [1] and further explained in a Eurachem Guide [2].

A balanced selection of tools

Quality related to technical work is dealt with in several ways and is specific to each laboratory. Thus EA-4/18 stresses that a laboratory should define its own level and frequency of PT participation after careful analysis of its other quality assurance (QA) measures, such as:

- Participation in method development and validation work;
- Experience from reference material (RM) characterization studies;
- Regular use of RMs or certified reference materials (CRM);
- Internal quality control (IQC);
- Internal studies, e.g. checks using independent techniques or analysis of blind samples;
- Participation in other interlaboratory comparisons.

These 'tools' are complementary but not perfect and they do not automatically ensure fit-for-purpose results! Important limitations should be identified, e.g. problems in obtaining a stable IQC sample or CRMs/RMs whose composition deviates from that of routine test samples. Also note that legislation may stipulate a minimum frequency of PT participation in certain areas. Frequently, some PT providers offer a flexible participation, e.g. 2, 4, 6 or 12 rounds/year; in rare cases, participation in PT may not be feasible at all.

Areas of technical competence

When planning PT participation, the laboratory starts the planning process by listing its areas of technical competence, defined in terms of three parameters:

- A measurement technique;
- A property;
- A product.

Two examples are "Quantitative real-time PCR (RT-qPCR) for the determination of DNA sequences of pathogens in meat" and "Inductively coupled plasma atomic emission spectroscopy (ICP-AES) for the determination of magnesium concentration in human serum".

An area of technical competence may encompass different, but equivalent and comparable, measurement techniques, different properties and/or different products. The laboratory can refer to the scope of a standardized procedure, or its method validation data, when planning its level of PT participation. If suitable PT schemes are available, the laboratory is expected to participate at least in a proficiency test related to each of its areas of technical competence.

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PT Leaflets

- **Five leaflets available**
  - Proficiency testing schemes
  - Pre- and post-analytical proficiency testing
  - How can proficiency testing help my laboratory
  - Selecting the right proficiency testing scheme for my laboratory
  - Proficiency testing – How much and how often?
- **Two new leaflets coming soon**
  - How to investigate poor performance in proficiency testing
  - Use of surplus proficiency test items
- **Available to download from Eurachem website**
  - www.eurachem.org/
  - Available in various European languages

Questions?

Thank you!